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Advance care planning in pediatric oncology

Submission date
13/01/2021

Recruitment status
No longer recruiting

Registration date
22/01/2021

Overall study status
Completed

Last Edited
14/05/2025

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In the adult population, advance care planning (ACP) has shown to improve communication around care planning. However, ACP tools or interventions for child and adolescent cancer patients are scarce and evidence is lacking. There is evidence that adolescent patients have the desire and ability to share their values, beliefs, and preferences for treatment at the end of life. Especially communication about topics such as “what to do if the adolescent should get significantly worse” remains difficult, leaving room for improvement.

Aiming to improve parent-adolescent communication about ACP topics, the study team has developed an intervention for adolescents with cancer and their parent(s). This study will assess the effectiveness of a pediatric ACP intervention (BOOST) for adolescents with cancer and their parent(s) in Belgium. In addition, there will be a process evaluation to evaluate the implementation, mechanisms of impact, and context of the intervention.

Who can participate?
Adolescents aged 10 -18 with any type of cancer in treatment at the pediatric oncology ward, and their parent(s).

What does the study involve?
The intervention group will receive the BOOST pACP intervention. The control group will receive care as usual.

The goal of the BOOST pACP intervention is to improve parent-adolescent communication on advance care planning topics. The BOOST pACP intervention involves three conversation sessions between a trained facilitator (external to the medical team) and an adolescent with cancer andtheir parent(s). Before the conversation sessions take place, the family receives preparation booklets. During the first conversation session, the facilitator will introduce the content of the upcoming conversation sessions to the adolescent and parent(s), by showing a short video and discussing two topics with conversation cards. The second conversation session takes place with the adolescent and parent(s) separately and is structured by conversation cards. Examples of topics discussed are “worries and fears” and “expectations for the future”. In the third conversation session, the adolescent and parent(s) will fill out a summary sheet together. If they give permission, the facilitator will share the summary sheet with their pediatric oncologist.

Adolescents and parents will fill out questionnaires on three occasions: before the study begins; after they have received the intervention (approximately 3 months after the study begins); and again at approximately 7 months after the study begins. The questionnaires will evaluate attitude, self-efficacy, intention, and communication with each other regarding ACP topics (among other determinants). The pediatric oncologist questionnaires evaluate the ACP topics they have talked about to the family and the ACP topics they are planning to talk about to the family in the near future.

A process evaluation will be conducted to evaluate how the intervention was implemented and to assess the experiences of different groups. The process evaluation entails monitoring during the data collection period and interviews with adolescents and parents after the intervention and with facilitators and healthcare professionals after the data collection period.

What are the possible benefits and risks of participating?
This study can deliver valuable evidence about the effects of ACP for adolescent cancer patients. The aim is to facilitate parent-child communication about ACP topics, in a way that adolescents feel empowered to engage more in their care plan. Talking about care preferences and open communication within families and with the medical team could improve a sense of control and autonomy.

It is possible participants will experience negative feelings, due to reflecting on potentially sensitive topics more than usual. However, these risks are minimal, taking into consideration that adolescents and parents are able to decide what topics they would like to discuss in the sessions. The study team will also monitor anxiety in adolescents and parents to allow a timely response to adverse events. The trained facilitator will give the contact information of the psychologist on the ward at the start of the conversation sessions and will emphasize they can always contact them when needed.

Where is the study run from?
Vrije Universiteit Brussels (VUB) and Ghent University (Belgium).

When is the study starting and how long is it expected to run for?
September 2018 to October 2023

Who is funding the study?
The Research Foundation- Flanders (Fonds Wetenschappelijk Onderzoek) and the Child Cancer Fund (Kinderkankerfonds) (Belgium)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

Nil known

Study information

Scientific Title
BOOST pACP: a multi-center randomized controlled trial to test the effectiveness of an advance care planning intervention on parent-adolescent communication in pediatric oncology

Acronym
BOOST pACP

Study objectives
1. Adolescents that receive the intervention will report better parent-adolescent communication (Parent-Adolescent Communication Scale (PACS) at T1 (baseline + 3 months), compared to adolescents that do not receive the intervention
2. Adolescents that receive the intervention will report better parent-adolescent communication (Parent-Adolescent Communication Scale (PACS) at T2 (baseline + 7 months), compared to adolescents that do not receive the intervention
3. Adolescents that receive the intervention will report better open communication and fewer problems in communication with their parent(s) (two subscales of Parent-Adolescent Communication Scale (PACS) at T1 (baseline + 3 months) and T2 (baseline + 7 months), compared to the adolescents that do not receive the intervention
4. Adolescents that receive the intervention, will report a more positive attitude towards, and better self-efficacy in communicating about ACP topics with their parent(s), at T1 (baseline +3 months) and T2 (baseline + 7 months), compared to adolescents that do not receive the intervention
5. Adolescents that receive the intervention, will report an intention to talk about more ACP topics and have talked about more ACP topics with their parent(s) at T1 (baseline +3 months) and T2 (baseline + 7 months), compared to adolescents that do not receive the intervention
6. Adolescents that receive the intervention, will report an intention to talk about more ACP topics and have talked about more ACP topics with their pediatric oncologist at T1 (baseline + 3 months) and T2 (baseline + 7 months), compared to adolescents that do not receive the intervention
7. Parent(s) that receive the intervention, will report a more positive attitude towards, and better self-efficacy in communicating about ACP topics with their child at T1 (baseline +3 months) and T2 (baseline + 7 months), compared to parent(s) that do not receive the intervention
8. Parent(s) that receive the intervention, will report an intention to talk about more ACP topics and have talked about more ACP topics with their child at T1 (baseline +3 months) and T2 (baseline + 7 months), compared to parent(s) that do not receive the intervention
9. Parents that receive the intervention will report a higher level of shared decision making (CollaboRATE) at T1 (baseline +3 months) and T2 (baseline + 7 months), compared to the parent (s) that do not receive the intervention
10. The intervention will be cost-effective (using the EQ-5D-Y) and cost-efficient (using resource use) at T1 (baseline + 3 months) and T2 (baseline + 7 months). We will carry out a subsequent economic evaluation

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 18/11/2020, Commission for Medical Ethics (O.G. 016) of the Vrije Universiteit Brussel /UZ Brussel (Laarbeeklaan 101, 1090 Brussels, Belgium; +32(0)24775584; commissie.ethiek@uzbrussel.be) Ref: 2020-270

Study design
Multicenter parallel-group randomized controlled superiority trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Improving communication on advance care planning (ACP) topics between adolescents with cancer and their parents

Interventions
Current intervention as of 04/05/2021:
The intervention group will receive the BOOST pACP intervention (Benefits of Obtaining Ownership Systematically Together), in addition to standard care. The control group will receive care as usual.

Two routes will be used to recruit patients:
1. Pediatric oncologists (together with psychologists) at each of the four participating wards will select adolescents based on the inclusion criteria first. Subsequently, they will review whether their parent(s) adhere to the inclusion criteria also.
2. Through patient organizations and other non-profit organizations. Organizations will be asked to post an open call in their newsletters, on their website and on other social media platforms (eg. Facebook, LinkedIn and/or Twitter) or share this in other ways that are common communication channels when interacting with their members and network. The research team has developed a flyer and social media image for organizations to share. Interested families can contact our data collectors.

The intervention group will be compared in terms of parent-adolescent communication to a usual care control group. Randomization will be performed per a computerized random number generator with a 1:1 allocation ratio to either the intervention arm or the standard care arm (control group) using simple randomization. Randomization will be stratified by age (two groups: 10-14 years versus 15-18 years).

The intervention consists of the following 10 components:
1. Training of facilitators that will lead the conversation sessions and coaching on the job every 3 months
2. Preparation booklets for the parent(s) and the adolescent
3. A video with experts by experience talking about the impact of the intervention (shown during the first conversation session)
4. Conversation session 1 involves an introductory session with parent(s) and adolescent together. Two broad topics (identity; experience of disease and treatment) are discussed with conversation cards.
5. Conversation session 2a, only with the adolescent, involves a conversation with the adolescent alone. Six ACP topics are discussed with conversation cards: talking to others; hope

and comfort; worries and fear; care preferences; expectations for the future; and about dying. Adolescents are asked to divide the topics into two categories: “I would like to discuss this topic with my parent(s)” and “at the moment I do not feel the need to discuss this topic with my parent (s)”.
6. Conversation session 2b, only with the parent(s), involves a conversation with the parent(s) alone. Seven ACP topics are discussed with conversation cards: talking to your child; parenthood; hope and comfort; worries and fear; care and treatment; expectations of the future; and about dying.
7. Conversation session 3 a conversation with parent(s) and adolescent together. They are given the opportunity to talk about certain ACP topics if they wish to.
8. The adolescent with parent(s) fill in a summary sheet together during the third conversation session. They can fill out whether they agree that this summary sheet is shared with their oncologist.
9. A transfer of information from the intervention facilitator to a treating pediatric oncologist /medical team, if families give permission
10. Conversation cards that can be used as a game of quartet at home. Families will receive conversation cards at the end of conversation session 3.

The conversation sessions are guided by a trained facilitator that has a background and experience as a psychologist, external to the treating medical team.

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Previous intervention:
The intervention group will receive the BOOST pACP intervention (Benefits of Obtaining Ownership Systematically Together), in addition to standard care. The control group will receive care as usual.

Pediatric oncologists (together with psychologists) at each of the four participating wards will select adolescents based on the inclusion criteria first. Subsequently, they will review whether their parent(s) adhere to the inclusion criteria also.

The intervention group will be compared in terms of parent-adolescent communication to a usual care control group. Randomization will be performed per a computerized random number generator with a 1:1 allocation ratio to either the intervention arm or the standard care arm (control group) using simple randomization. Randomization will be stratified by age (two groups: 10–14 years old versus 15–18 years old).

The intervention consists of the following 10 components:
1. Training of facilitators that will lead the conversation sessions and coaching on the job every 3 months
2. Preparation booklets for the parent(s) and the adolescent
3. A video with experts by experience talking about the impact of the intervention (shown during the first conversation session)
4. Conversation session 1 involves an introductory session with parent(s) and adolescent together. Two broad topics (identity; experience of disease and treatment) are discussed with conversation cards.
5. Conversation session 2a, only with the adolescent, involves a conversation with the adolescent alone. Six ACP topics are discussed with conversation cards: talking to others; hope and comfort; worries and fear; care preferences; expectations for the future; and about dying. Adolescents are asked to divide the topics into two categories: “I would like to discuss this topic with my parent(s)” and “at the moment I do not feel the need to discuss this topic with my parent

(s)".
6. Conversation session 2b, only with the parent(s), involves a conversation with the parent(s) alone. Seven ACP topics are discussed with conversation cards: talking to your child; parenthood; hope and comfort; worries and fear; care and treatment; expectations of the future; and about dying.
7. Conversation session 3 a conversation with parent(s) and adolescent together. They are given the opportunity to talk about certain ACP topics if they wish to.
8. The adolescent with parent(s) fill in a summary sheet together during the third conversation session. They can fill out whether they agree that this summary sheet is shared with their oncologist.
9. A transfer of information from the intervention facilitator to a treating pediatric oncologist /medical team, if families give permission
10. Conversation cards that can be used as a game of quartet at home. Families will receive conversation cards at the end of conversation session 3.

The conversation sessions are guided by a trained facilitator that has a background and experience as a psychologist, external to the treating medical team.

Intervention Type
Behavioural

Primary outcome(s)
1. Parent-adolescent communication from the perspective of the adolescent, measured by the Parent-Adolescent Communication Scale (PACS) (Dutch translation by translation agency for this study) at baseline, 3, and 7 months

Key secondary outcome(s))
1. Adolescent attitude, self-efficacy, behavior, and intention to communicate about ACP topics with parent(s), measured using self-developed items constructed based on the Theory of Planned Behavior at baseline, 3, and 7 months
2. Adolescent behavior and intention to communicate about ACP topics with a pediatric oncologist, measured using self-developed items (constructed based on the Theory of Planned Behavior) at baseline, 3, and 7 months
3. Adolescent quality of life (for cost-effectiveness), measured using the EuroQol 5-dimension quality of life questionnaire (EQ-5D-Y) at baseline, 3, and 7 months
4. Adolescent satisfaction items and items on perceived effect only for the intervention group (on intervention components and the intervention as a whole) measured using self-developed items at 3 and 7 months
5. Parent(s) attitude, self-efficacy, behavior and intention to communicate about ACP topics with their child, measured using self-developed items (constructed based on the Theory of Planned Behavior) at baseline, 3, and 7 months
6. Parent(s) perspective of the level of shared decision making in the last clinical encounter with the pediatric oncologist, measured using the CollaboRATE for parents at baseline, 3, and 7 months
7. Parent(s) satisfaction items and items on perceived effect only for the intervention group (on intervention components and the intervention as a whole) measured using self-developed items at 3 and 7 months
8. Pediatric oncologists behavior and intention to communicate about ACP topics with the family, measured using self-developed items (constructed based on the Theory of Planned Behavior) at baseline, 3, and 7 months
9. Level of anxiety the past week measured using the Patient-Reported Outcomes Measurement

Information System (PROMIS) in the questionnaires for adolescents and parents at baseline, 3, and 7 months
10. Perceived effects of the intervention measured using semi-structured face-to-face interviews with a selection of adolescents and parent(s) at 5 months

Process evaluation outcome measures:
1. Fidelity measured by:
1.1. Analysis of a selection of audio-recorded conversation sessions of the facilitators with the adolescent and parent(s), to analyze fidelity at facilitator level throughout the data collection period
1.2. Analysis of reports of coaching on the job sessions for facilitators (what actions have been done and have the actions been done at the right time?) every 4 months
1.3. Structured diary filled in by facilitators (present during conversation sessions) about what topics were and were not discussed, kept updated continuously and completed at 3 months
2. Experiences of different groups measured by:
2.1. Separate interviews with adolescents and parents (about suitability, feasibility, added value) at 5 months
2.2. Interviews with facilitators (about challenges, facilitating factors, proposed changes, feasibility), after the data collection period
2.3. Interviews with healthcare professionals at the pediatric oncology ward through interviews (about the transfer of information of facilitator and potential courses on communication, ACP or palliative care), after the data collection period
3. Evaluating recruitment and enrollment into the study (number of eligible patients and parent (s) approached, reasons for not approaching, number of approached families that were recruited, number and characteristics of patients that refused to participate and reasons for refusal) at baseline

Completion date
31/10/2023

Eligibility

Key inclusion criteria
Adolescent (patient):
1. Aged between 10 and 18 years
2. Diagnosis of cancer ≥ 3 months prior to inclusion
3. Aware of, or informed about, cancer diagnosis according to parent(s)
4. Receiving treatment in a pediatric oncology ward
5. Fluent Dutch language understanding

Parent:
1. Aware of or informed about the diagnosis of their child according to the clinician
2. Fluent Dutch language understanding

Pediatric oncologist:
1. Medically involved in the treatment of the adolescent
2. Indicated by the family to be the oncologist with whom the family has most contact about treatment
3. Fluent Dutch language understanding

Healthy volunteers allowed

No

Age group
Mixed

Sex
All

Key exclusion criteria
Adolescent (patient):
1. Participated in the feasibility test
2. Intellectual disabilities to an extent that general communication is very difficult or heavy mental health problems to an extent that the extra effort of participating in the study is not justified (estimated by the pediatric oncologist and psychologist)
3. Life expectancy ≤3 months
4. Not receiving active treatment (in follow up or in remission)

Parent:
1. Participated in the feasibility test
2. Intellectual disabilities to an extent that general communication is very difficult or heavy mental health problems to an extent that the extra effort of participating in the study is not justified (estimated by the pediatric oncologist and psychologist)

Date of first enrolment
28/01/2021

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
Belgium

Study participating centre
University Hospital Brussels
Brussels Health Campus
Laarbeeklaan 101
Jette
Belgium
1090

Study participating centre
University Hospital Leuven
Herestraat 49

Leuven
Belgium
3000

Study participating centre
University Hospital Antwerp
Drie Eikenstraat 655
Edegem
Belgium
2650

Study participating centre
University Hospital Ghent
Corneel Heymanslaan 10
Gent
Belgium
9000

Study participating centre
Vrije Universiteit Brussel
Laarbeeklaan 101
Jette
Belgium
1090

Study participating centre
Universiteit Gent
Campus UZ Gent
Corneel Heymanslaan 10
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Sponsor information

Organisation
Vrije Universiteit Brussel

ROR

https://ror.org/006e5kg04

Funder(s)

Funder type
Research organisation

Funder Name
Fonds Wetenschappelijk Onderzoek

Alternative Name(s)
Research Foundation Flanders, Flemish Research Foundation, Research Foundation – Flanders, Fonds voor Wetenschappelijk Onderzoek - Vlaanderen, The FWO, Het FWO, FWO

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Belgium

Funder Name
Kinderkankerfonds (Child Cancer Fund)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request. Sharing of datasets will be defined on a case-by-case basis. Requests may be addressed to the main contact persons (Anne van Driessche, Prof. Kim Beernaert, Prof. Joachim Cohen). Every request will be evaluated on an individual basis and the ethics committee of the Vrije Universiteit Brussels will be contacted for approval before any sharing of participant-level data.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		29/01/2025	05/02/2025	Yes	No
Results article		13/05/2025	14/05/2025	Yes	No
Protocol article		01/09/2021	13/02/2023	Yes	No

Study website	Study website	11/11/2025	11/11/2025	No	Yes